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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,587	02/12/2001	Anders Hjelholt Pedersen	0212us310	9481

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MAXYGEN, INC.
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EXAMINER

TELLER, ROY R

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 03/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/782,587

Applicant(s)

PEDERSEN ET AL.

Examiner

Roy Teller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-67 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following is required under 35 U.S.C. 121:

I. Claims 1-56, and 63, drawn to a conjugate of wild-type FVII or FVIIa, classified in class 530, subclass 350.

II. Claim 57, drawn to a polypeptide, classified in class 530, subclass 350.

III. Claims 58-61, drawn to a nucleotide, expression vector and host cell, classified in class 536, subclass 23.1, class 435, subclass 320.1, and class 435, subclass 325.

IV. Claim 62, drawn to a method of producing the conjugate, classified in class 530, subclass 350.

V. Claims 64-67, drawn to a method of treatment, classified in class 530, subclass 350.

This application also contains claims directed to the following patentably distinct species of the claimed invention:

Select **one** attachment group: lysine, cysteine, aspartic acid, or glutamic acid.

Select **one** from: K18, K32, K38, K62, K85, K109, K137, K143, K148, K157, K161, K197, K199, K316, K337, K341, or K389.

Select **one** from: R, Q, N, or H.

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Select **one** from: I42K, Y44K, L288K, D289K, R290K, G291K, A292K, T293K, Q313K, S314K, R315K, V317K, L390K, M391K, R392K, S393K, E394K, P395K, R396K, P397K, G398K, V399K, L400K, L401K, R402K, A403K, P404K, or F405K.

Select **one** from: I30C, K32C, D33C, A34C, T37C, K38C, W41C, Y44C, S45C, D46C, L141C, E142C, K143C, R144C, L288C, D289C, R290C, G291C, A292C, S314C, R315C, K316C, V317C, L390C, M391C, R392C, S393C, E394C, P395C, R396C, P397C, G398C, V399C, L401C, R402C, A403C, or P404C.

Select **one** from: I30D/E, K32D/E, A34D/E, T37D/E, K38D/E, W41D/E, Y44D/E, S45D/E, D46C, L141D/E, E142D/E, K143D/E, R144D/E, L288D/E, R290D/E, G291D/E, A292D/E, Q313D/E, S314D/E, R315D/E, K316D/E, V317D/E, L390D/E, M391D/E, R392D/E, S393D/E, P395D/E, R396D/E, P397D/E, G398D/E, V399D/E, L401D/E, R402D/E, A403D/E, or P404D/E.

Select **one** from: D33, D46, D48, E77, E82, D86, E94, E99, D104, E116, D123, E132, E142, E163, D196, E210, D212, E215, D217, D219, E220, D256, E265, E270, D289, E296, D309, D319, E325, D334, D338, D343, E385, or E394.

Select **one** non-polypeptide moiety from: linear polyethylene glycol, branched polyethylene glycol, polyvinyl alcohol, polycarboxylic acid, or poly (vinylpyrrolidine)

Select **one** from : F4S/T, P10N, Q21N, W41N, S43N, A51N, G58N, L65N, G59S/T, E82S/T, N95S/T, G97S/T, Y101N, D104N, T106N, K109N, G117N, G124N, S126N, T128N, A175S/T, G179N, I186S/T, V188N, R202S/T, I205S/T, D212N, E220N, I230N, P231N, P236N, G237N, V253N, E265N, T267N, E270N, R277N, L280N, G291N, P303S/T, L305N, Q312N,

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G318N, G331N, D334N, K334N, G342N, H348N, R353N, Y357N, I361N, V376N, R379N, or M391N.

Select **one** from: K32N+A34S/T, F31N+D33S/T, I30N+K32S/T, A34N+R36S/T, K38N+F40S/T, T37N+L39S/T, R36N+K38S/T, L39N+W41S/T, F40N+I42S/T, W41N+I42N+Y44S/T, S43N, Y44N+D46S/T, S45N+G47S/T, D46N+D48S/T, G47N+Q49S/T, K143N+N145S/T, E142N+R144S/T, L141N+K143S/T, I140N+E142S/T, R144N+A146S/T, A146N+K148S/T, S147N+P149S/T, R290N+A292S/T, D289N+G291S/T, L288N+R290S/T, L287N+D289S/T, G291N, A292N+A294S/T, T293N+L295S/T, R315N+V317S/T, S314N+K316S/T, Q313N+R315S/T, Q312N, K316N+G318S/T, V317N+D319S/T, G318N, K341N+D343S/T, S339N+K341S/T, G342N, D343N+G345S/T, R392N+E394S/T, M391N, L390N+R392S/T, K389N+M391S/T, S393N+P395S/T, E394N+R396S/T, P395N+P397S/T, R396N+G398S/T, P397N+V399S/T, G398N+L400S/T, V399N+L401S/T, L400N+R402S/T, L401N+A403S/T, R402N+P404S/T, A403N+F405S/T, P404N+P406S/T, or K143N+N145S/T+R315N+V317S/T.

Applicant is advised that this is a restriction and not an election of species. Amendment of the claims to delete non-elected subject matter is required prior to allowance.

The inventions are distinct, each from the other because of the following reasons:

The inventions of group I, II, and III are patentably distinct from each other because they are drawn to different structures having different functions. The conjugate of group I is composed of a polypeptide and a non-polypeptide moiety. The polypeptide of group II does not contain the non-polypeptide moiety of group I, thus giving it a different structure. The nucleic acid of group III is composed of deoxyribonucleotides linked by phosphodiester bonds and

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assumes the form of a double helix. Consequently, the structures of each invention are different and patentably distinct.

The inventions of groups IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP808.01). In the instant application, the different inventions have different effects. The invention of group IV is a method of producing the conjugate, while the invention of group V is a method of treatment using a form of the conjugate. Consequently, the inventions are patentably distinct due to their different effects.

Upon election of an invention from groups I-V above, applicant must further elect a patentably distinct sequence. **This is not an election of species.** Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. Polypeptide sequences are also structurally distinct compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide and polypeptide sequence are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 UCS 121 and 37 CFR 1.141.

Should applicant traverse on the ground that the sequences are not patentably distinct, applicant should submit or identify such evidence now of record showing the sequences to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the prior invention.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because the restriction/ election requirement is complex, a telephone call to applicant's attorney to request an oral election was not made. See MPEP 812.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirements be traversed. See 37 CFR 1.143.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703) 305-4243. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RT
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3/18/03

RT


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